

APR 5 - 2007

K070245

[on letterhead]

## **510(k) Summary CapSure™ PS System**

### **1. Submitter Information**

Spine Wave, Inc.  
Two Enterprise Drive  
Suite 302  
Shelton, CT 06484  
Telephone: 203-944-9494  
Telefax: 203-944-9493

Contact: Ronald K. Smith  
Date Prepared: January 24, 2007

### **2. Device Information**

Trade Name: CapSure™ PS System  
Common Name: Pedicle Screw Spinal System  
Classification: Class II per 21 CFR 888.3070  
Classification Name: Pedicle Screw Spinal System  
Product Code: MNH, MNI

### **3. Device Information**

The CapSure™ PS System consists of a selection of non-sterile, single use titanium alloy rod and screw components that are assembled to create a rigid spinal construct. The rod and screw components of the CapSure™ PS System are attached to the non-cervical spine in order to stabilize the spine during fusion of the vertebral bodies, and are intended to be removed after spinal fusion is achieved.

### **4. Intended Use**

When used as a pedicle screw fixation system of the noncervical spine in skeletally mature patients, the CapSure™ PS System is indicated for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

The CapSure™ PS System is also indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebral joint, having fusions with autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation

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pg 1 of 2

are L3-S1), and for whom the device is intended to be removed after solid fusion is attained.

## **5. Substantial equivalence<sup>1</sup>**

The CapSure™ PS System is substantially equivalent to the Moss Miami Spinal System (K030383), the Issys Pedicle Screw System (K043522), and the ST360™ Spinal Fixation System (K041925). Mechanical testing according to ASTM F1717 demonstrated that the CapSure™ PS System has substantially equivalent mechanical properties to the predicate Moss Miami Spinal System. Since the CapSure™ PS System is substantially equivalent in intended use, design, materials, and construction to the predicate devices, the CapSure™ PS System does not raise any new issues of safety and efficacy when compared to these legally marketed devices.

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<sup>1</sup> Use of the terms "substantially equivalent" and "substantial equivalence" in this application is intended only to denote a comparison of the subject device to predicate devices for the purpose of an FDA review of the safety and effectiveness of the subject device in accordance with 21 CFR 807. Statements comparing the subject device to predicate devices, including statements regarding "substantial equivalence", contained herein are not intended in any way to relate to patentability, patent infringement, or any analysis of the subject device under foreign or United States patent laws including 35 U.S.C. paragraph 100 et seq. or related judicial doctrines.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**APR 5 - 2007**

Spine Wave, Inc.  
% Mr. Ronald K. Smith  
Director, Quality and Regulatory Affairs  
Two Enterprise Drive, Suite 302  
Shelton, Connecticut 06484

Re: K070245  
Trade/Device Name: Capsure™ PS System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class II  
Product Code: MNI, MNH  
Dated: March 23, 2007  
Received: March 26, 2007

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Ronald K. Smith

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over a horizontal line.

Mark N. Melkerson

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known): K070245

Device Name: CapSure™ PS System

Indications for Use:

When used as a pedicle screw fixation system of the noncervical spine in skeletally mature patients, the CapSure™ PS System is indicated for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

The CapSure™ PS System is also indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebral joint, having fusions with autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3-S1), and for whom the device is intended to be removed after solid fusion is attained.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

And / Or

Over-The-Counter-Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE  
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

Page 1 of 1

510(k) Number K070245

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